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**Sent:** 12/18/2018 12:58:45 PM  
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**Subject:** Despite Past Filings, Sterigenics Avoids Filing Reports To EPA's TRI - Inside EPA

## Despite Past Filings, Sterigenics Avoids Filing Reports To EPA's TRI

December 17, 2018

Sterigenics, the sterilization company at the center of a controversy in the Chicago area over its releases of ethylene oxide (EtO), appears to have dropped its past practice of filing emissions data to EPA's Toxics Release Inventory (TRI) database for 2017 for any of its facilities, according to searches performed by *Inside EPA*.

According to EPA, the agency has posted 2017 data for hundreds of facilities in its TRI database, though searches of the database find no results for Sterigenics facilities in 2017, even though such reports were due to EPA by July 1.

By contrast, searching data in the TRI database for 2006-2016 provides emissions reports from nine Sterigenics facilities across the U.S., in California, Georgia, Illinois, North Carolina, New Mexico, New York, Texas and Utah.

For example, in 2016, the Willowbrook, IL, facility reported 4,205 pounds of EtO air releases, down from 4,899 pounds in 2015.

While such levels appear to fall below EPA's typical reporting threshold of 10,000 pounds, the company has filed such data for years but now appears to have stopped the practice.

A Sterigenics spokesperson says the company is not required to file TRI reports for its facilities but did not explain why, or why the company appears to have changed its practices. Several of Sterigenics' facilities have filed TRI Form R reports annually as far back as 1987.

An EPA spokesperson gave no specifics about Sterigenics' 2017 data, but provided some scenarios in which a facility would not have to report to TRI, such as if its status changed to exempt it from reporting.

"A facility might not report for a given year because it determined that it did not meet one [of the] requirements. ... each year hundreds of facilities come into and out of the TRI regulatory scheme due to threshold determinations. Each year, EPA conducts data quality analyses and reviews changes in reporting."

Regardless, the lack of information could intensify national controversy over the adequacy of EPA's regulation of the chemical's releases and local uncertainty about the risks communities in the Chicago-area face from the company's emissions of EtO, a known carcinogen, as they await a promised EPA risk assessment in 2019.

EtO is commonly used as an intermediate to make other chemical products like detergent, antifreeze and polyester, and to sterilize medical equipment and foods, though the chemical has long been suspected of causing breast and lymph cancers.

EPA's 2016 Integrated Risk Information System (IRIS) assessment of EtO affirmed those links and classified the substance as a known carcinogen. It also recommended conservative risk values that are expected to drive stricter regulatory standards.

Sterigenics and its use of EtO to sterilize medical equipment and devices came to widespread attention in recent months after EPA's release last August of modeling emissions data in its latest National Air Toxics Assessment (NATA) covering 2014 emissions. When combined, the NATA data and IRIS assessment prompted EPA to announce earlier this year that it would review its air toxics rules for EtO.

In addition, an assessment by the Agency for Toxic Substances Disease Registry also suggested high cancer risk in the area around the Illinois plant.

EPA's Office of Inspector General (OIG) announced Dec. 17 that it is launching a review of whether EPA has taken sufficient steps to mitigate cancer risks presented by EtO and other harmful chemicals in its air toxics rules.

But the chemical industry has filed a request for correction with EPA under the Information Quality Act (IQA) asking the agency to withdraw EtO data in the NATA that relied on its 2016 IRIS values for the chemical.

### Stricter Rules

Officials representing communities near the Illinois Sterigenics plant, however, have been urging EPA to clamp down on the facility's emissions and to strengthen its rules governing EtO. In October, Sens. Dick Durbin (D-IL) and Tammy Duckworth (D-IL), as well as Rep. Bill Foster (D-IL), spelled out a series of steps they wanted the agency to take to more strictly regulate EtO under the Clean Air Act and the Toxic Substances Control Act.

The controversy has done little to quell local concerns, especially after EPA indicated over the Thanksgiving weekend that it may have overstated the amount of EtO in the air near the Sterigenics facility.

The agency is now gathering and analyzing emissions monitoring data as part of an effort to complete a risk analysis for the Willowbrook community, which EPA's air chief Bill Wehrum promised will be completed in 2019. In addition, the agency also recently began conducting water sampling for EtO, according to a local CBS affiliate.

But the missing TRI data could inform the pending analysis.

TRI, created by section 313 of the Emergency Planning and Community Right-To-Know Act of 1986 (EPCRA), requires industrial facilities in a host of sectors to report annual releases of a specified set of more than 650 chemicals.

The agency places all the information in a public, searchable database on its website and also releases an annual "National Analysis" report on the latest year's data.

The law generally requires the data for the prior calendar year to be reported by July 1 of the following year and provides a \$25,000 per day penalty for missing the reporting deadline.

Last October, OIG announced that it is beginning a review of how the agency addresses situations in which companies who are required to report to TRI do so after the statutory deadline. In an Oct. 4 memo to EPA enforcement chief Susan Bodine, a top OIG

official explains that the “project objective will address whether the EPA is taking enforcement actions against companies that delay required reporting of chemical release data to EPA’s TRI.”

TRI is one source for data used in NATA. While NATA is released every few years, TRI is released annually. Its data source is also uniform, allowing comparison over time and between different parts of the country -- as EPA produces with its National Assessments. Such analyses cannot be performed with NATA data, which varies in detail between states and over time in its analyses.

Sterigenics' plants are not the top producers of EtO in terms of pounds of emissions, according to TRI reports from 2006-2016.

Sterigenics' facility in Santa Teresa, NM, ranks number 12 in the country for facilities that reported EtO releases to TRI between 2006 and 2016, with more than 111,300 pounds released over that decade, according to EPA's EasyRSEI Dashboard.

Sterigenics' Willowbrook facility ranks 21st in this category, with more than 57,600 pounds of emissions over that decade. But when ranked by Risk-Screening Environmental Indicators (RSEI) score, two of Sterigenics' facilities are in the top 10 for the 2006-2016 decade: Willowbrook has the fourth highest RSEI score for the nation in that decade, while Sterigenics' facility in Atlanta ranks ninth.

EPA's website explains that “RSEI scores add context to chemical release data reported by facilities to the [TRI] by considering the size of the chemical release, the fate and transport of the chemical through the environment, the size and location of the exposed population, and the chemical's toxicity. RSEI Scores are available for modeled releases and transfers (air releases, water releases, and transfers to POTWs and off-site incineration).” The scores, which are “unitless values” are “calculated as toxicity weight multiplied by the exposed population multiplied by the estimated dose.” The scores “are only meaningful in comparison to other RSEI Scores.”

In the case of the list of facilities reporting emissions of EtO in the U.S., the size of the exposures and the exposed population represent the differences in the RSEI score.

The Willowbrook facility is touting new pollution control devices it installed last summer after the release of the NATA information, which it says ensure the facility captures 99.9 percent of EtO used. The company has also questioned EPA's analysis of the monitoring results -- after EPA last month acknowledged errors in its emissions testing -- as well as the soundness of the IRIS assessment. They also argue EtO's use as a sterilizer is critical because it is the only way some medical devices can be sterilized without damaging them